



Docket: A-1028con

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

531-00

In re Application of:
Foerster et al.

Group Art Unit: 3764

Serial No: 08/858,389

Filed: May 19, 1997

Examiner: B. Koo

For: DEVICES FOR MARKING AND DEFINING
PARTICULAR LOCATIONS IN BODY
TISSUE

#17
Recons

Assistant Commissioner for Patents
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Washington, D.C. 20231

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REQUEST FOR RECONSIDERATION

Sir:

This request for reconsideration is responsive to the Examiner's Office Action of February 15, 2000.

Applicants gratefully acknowledge the Examiner's indication that claim 17 is allowed, and that claim 45 is objected to, and would be allowed if rewritten in independent form.

The Examiner's comment that Applicants' amendment to claim 6 is moot, since claim 6 was previously withdrawn from further consideration as being drawn to a non-elected species, is noted. However, Applicants respectfully submit that the amendment is not moot should claim 6 ultimately be found to be dependent upon an allowed claim, in which case the claim will be allowed as well, even though non-elected, per PTO practice. Therefore, the amendment should be duly entered.

Claims 1, 15, 16, 35-37, 43, and 44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Komiya '576, Kirsch et al. '240, and Miller et al. '269. The basis for rejection is unclear, to the extent that it is unclear how the Examiner is proposing that

the teachings of the various applied references be combined to meet the claim limitations. Presumably, the Examiner intended the rejection to be over Komiya '576 in view of Kirsch et al. '240 and Miller et al. '269. Applicants' rebuttal is predicated on that presumption. If this is an incorrect understanding, Applicants respectfully request a further non-final office action which clearly states the basis for rejection of the claims, as required under the holding of *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966).

As stated in the prior response, filed on November 29, 1999, claim 1 is clearly allowable over this combination of references. Essentially, Applicants strongly disagree with the Examiner's assertion that it "would have been obvious to have used the deployment means of Kirsch et al. (in the Komiya '576 device, presumably) because both types would be considered art-recognized alternative structures." While one may argue that Komiya '576 and Kirsch et al. '240 both disclose "art-recognized alternative structures" for deploying surgical clips, that does not automatically mean that it would have been obvious to substitute one mechanism for the other. In fact, Applicants assert that there would have been no motivation for one to have used the deployment actuator mechanism of Kirsch et al. in the Komiya device, absent specific reference to Applicants' disclosure. Structurally, the Kirsch et al. and Komiya deployment mechanisms are entirely different in operation, and have a very different purpose. Practically, one would need to replace practically the entire deployment structure of Komiya with that of Kirsch et al. to effect the change. However, to do so would be to destroy the function of Komiya, which is to incorporate a structure which permits, by virtue of a unique interaction of elements, the clip member 11 to become much wider than the delivery tube 21, so that it can clip a large tissue portion 22 to be clamped. For example, as set forth in the Komiya patent at col. 5, lines 39-51, a unique benefit of the Komiya mechanism is that the clamping portions 11d of the clip member 11 can be opened wide by engaging the

offset portions in b of the clip member 11 with the inner surface of the holder 21, so that "a greater affected portion of the body cavity can be clipped...". See also, Figs. 6 and 7 of the Komiya patent, which show this unique feature. In contrast, the Kirsch et al. mechanism does not include a capability to open the jaws of the clip mechanism wider than the surrounding body 56, because such a feature is not necessary for anastomosis applications.

As stated by the Board of Appeals in *Ex Parte Hartmann*, 186 U.S.P.Q. 366 (1974), references are not properly combined when such combination would destroy that on which the invention of one of the references is based. Since the Examiner's proposed substitution of the Kirsch et al. deployment structure for that of Komiya would, in essence, destroy the unique functionality of Komiya, as discussed supra, and since such combination is motivated solely by reference to Applicants' disclosure (and therefore improper hindsight reconstruction, see, for example, *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303 (Fed. Cir. 1983)), the proposed substitution is improper, and the rejection should therefore be withdrawn.

Additionally, even if, *arguendo*, a combination of Komiya and Kirsch et al. would have been obvious, the combination, even in combination with the further teachings of Miller et al., would not have met the claim 1 limitations. The Examiner is interpreting the element 19 of Komiya as the claimed deployment actuator connector (he also says element 10 is the deployment actuator, but this makes little sense, so is believed to be an error), and holes 21 as the claimed forming die. Presumably, the claimed "member" is either element 10 or perhaps element 15. These are the only two possibilities. However, this interpretation does not meet the claim limitations. Specifically, claim 1 recites that the "connector" extends both distally and proximally of the "member". Both elements 10 and 15 could meet this limitation. However, the claim also requires that the claimed "member" function as a "forming die" for the marker

element. Obviously, neither of the elements 10 and 15 meet this requirement, nor would it have been obvious to modify them to meet this requirement, without reference to Applicants' disclosure. If there is a "forming die" as disclosed by Komiya, it would be holes 21, which are distal of the distal-most end of the connector 19, and thus do not meet the claim limitation discussed supra.

Of course, the structure of Komiya as modified by the Kirsch et al. teachings must be considered when reading claim 1 thereon, if the assumption is first made, for purposes of argument, that such a combination would have been obvious. If such a substitution is made, element 15 of Komiya is removed, since its sole purpose is as an actuating member for the Komiya mechanism, and would be unnecessary for the Kirsch et al. mechanism. The only reasonable approach would be to remove all elements shown in Komiya, except for the clip 11 and the cannula 10, and substitute all of the elements of Kirsch et al. If that were done, the jaws 56 of Kirsch et al., as substituted into the Komiya device, would be the only elements potentially readable as the recited "member" in claim 1. However, this interpretation is untenable, for example, because the connector 50, 19 of Kirsch et al. does not extend distally of the jaws 56, as required by the language of claim 1.

Therefore, it is abundantly clear that the rejection of claim 1 on the grounds set forth by the Examiner is improper, and should be withdrawn, both because it would not have been obvious to apply the teachings of Kirsch et al. to those of Komiya absent reference to Applicants' disclosure, and because, even if such a combination were made, the combined teachings would not have met the claim limitations.

Claims 15, 16, and 35-37 are dependent upon claim 1, and are therefore allowable as well.


Independent claim 44 is allowable for the reasons discussed supra, with respect to claim 1. Claim 43 is dependent upon allowable claim 44, and is therefore also

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allowable.

In view of the foregoing amendments, and supporting remarks, Applicants respectfully submit that the application is now in condition for allowance over the prior art of record, and early notification of same is earnestly solicited. Should there remain further issues to be addressed, the Examiner is respectfully requested to contact the undersigned at the below listed number.

Respectfully submitted,


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May 15, 2000
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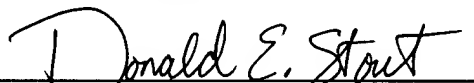
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Date: 5-15-00